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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/538,514 | 06/09/2005 | Tsuyoshi Naganuma | Q88061 | 1878 |

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| EXAMINER | |
|---|---|
| WEBB, WALTER E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 4133 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/538,514 | NAGANUMA ET AL. | |
| | Examiner | Art Unit | |
| | Walter E. Webb | 4133 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of Claims

Claims 1-12 and 14-26 are pending and rejected.

Claim 13 has been canceled.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite with regard to the formula for the indoline compound. There is no formula after the colon on line 3 of the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 16-18 rejected under 35 U.S.C. 102(b) as being anticipated by Kitazawa et al., (US 5,387,603).

Applicant's invention is drawn to a solid oral dosage form for the treatment of dysuria comprising the compound of claim 1 (KMD-3213) (claims 1, 16-18), where the solid form has a dissolution time according to the method of Japanese pharmacopoeia (claims 1-4). The pharmaceutical further comprises D-mannitol (claims 5, 22), magnesium stearate (claims 6-9 and 24-26), sodium lauryl sulfate (claims 9 and 26). The dosage is in tablet or capsule form (claims 10 and 19), where the capsule or tablet has a light shielding containing titanium oxide (claims 11, 12 and 19-21).

Kitazawa et al. teach the compound of claim 1 (KMD-3213) (see col. 62, claim 10), and a method of using the compound for the treatment of dysuria (see col. 1, lines 57-59.). They also teach that the compound or the pharmaceutically acceptable salts thereof can be administered orally as tablets and capsules in accordance with conventional molding methods (see col. 16, lines 15-23).

The conventional molding methods would inherently include the dissolution time according to Japanese pharmacopoeia. (See Ishihara et al., (US 2002/0177593) at paragraphs [0619].)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitazawa et al., (US 5,387,603) in view of Ishihara et al., (US 2002/0177593).

Applicant's invention is drawn to a solid oral dosage form for the treatment of dysuria comprising the compound of claim 1 (KMD-3213) (claims 1, 16-18), where the solid form has a dissolution time according to the method of Japanese pharmacopoeia (claims 1-4). The pharmaceutical further comprises D-mannitol (claims 5, 22), magnesium stearate (claims 6-9 and 24-26), sodium lauryl sulfate (claims 9 and 26). The dosage is in tablet or capsule form (claims 10 and 19), where the capsule or tablet has a light shielding containing titanium oxide (claims 11, 12 and 19-21). Claim 1 further comprises at least one member selected from the group consisting of $\alpha_1$-

adrenoceptor blocking agent, an anticholinergic agent, an anti-inflammatory agent and an antibacterial agent (claims 14 and 15).

Kitazawa et al. teach the compound of claim 1 (KMD-3213) (see col. 62, claim 10), and a method of using the compound for the treatment of dysuria (see col. 1, lines 57-59.). They also teach that the compound or the pharmaceutically acceptable salts thereof can be administered orally as tablets and capsules in accordance with conventional molding methods (see col. 16, lines 15-23.

Kitazawa et al. does not teach combining the compound with at least one member selected from the group consisting of $\alpha_1$-adrenoceptor blocking agent, an anticholinergic agent, an anti-inflammatory agent and an antibacterial agent, and other ingredients: mannitol, magnesium stearate, sodium lauryl sulfate, and titanium oxide.

Ishihara et al. teach a method for treating dysuria with agents for further improving excretory potency of the urinary bladder. (See Abstract (57).) Agents include KMD-3213 and other compounds like the anticholinergic agent mazaticol (see paragraphs [0559], [0553], [0556], and [0577].) They teach that these agents can be administered in capsule or tablet form further comprising a light-shielding coating agent like titanium oxide, D-mannitol, magnesium stearate, and sodium lauryl sulfate (see paragraphs [0618], [0626], [0620], and [0596].

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to combine the compound of Kitazawa with the anticholinergic agent (mazaticol) of Ishihara since both compounds are used to treat dysuria (see Ishihara at [0553], [0556] and [0577]). Moreover, "[i]t would be prima facie obvious to

combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." *In re Kerkhoven* 206 USPQ 1069, 1073. Thus, combining KMD-3213 with a with an anticholinergic agent, as claimed in the instant invention, sets forth prima facie obvious subject matter.

It would have also been obvious to a person having ordinary skill in the art to incorporate into the tablet or capsule of Kitazawa titanium oxide, D-mannitol, magnesium stearate, and sodium lauryl sulfate, since Ishihara teach that adding these ingredients into the capsule or tablet would comply with conventional molding methods in the field of formulation technology (see Ishihara at paragraph [0619]).

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

WW

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER